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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,933	09/20/2001	Luba Cohen	2786-0191P	9933

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EXAMINER	
WARE, DEBORAH K	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,933	COHEN, LUBA	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *9/20/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are presented for examination on the merits.

Response to Amendment

The amendment filed November 24, 2004, in response to the prior Office action filed September 8, 2004, has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-5, 7, 10-11, 13, 16-17, 19 and 22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Fuhrman et al, cited of record, for those reasons set forth in the prior Office action noted above, filed September 8, 2004.

Response to Arguments

Applicant's arguments filed November 24, 2004, have been fully considered but they are not persuasive. Applicant has presented two copies of articles noted at pages 9 and 10 of the instant response, of which they state "rebuts the theory of inherency suggested by the Examiner". However, it is not a theory that oxidative damage by free radicals causes disease, or conditions therefore, because Fuhrman clearly teaches at page 267, column 1, "INTRODUCTION" section, lines 1-3 in said section, oxidative damage by free radicals is the cause of diverse diseases, including cancer and cardiovascular disease.

With respect to the first noted article at page 9 of the instant response, "Controlled Trials in Cardiovascular Medicine", the article is directed to vitamin E

supplementation in randomized clinical trials of which the rate of lipid peroxidation was near normal in a large proportion of subjects in the trials, and not direct administration of Licorice extract to a patient as claimed herein. The instant claims are not disclosed to have been tested in randomized clinical trials but are disclosed at bridging pages 5-6 to have been studied through contolled experimentation. Such a controlled environment would have been expected to provide for successful results, and further, the article is not even discussing the use of licorice extract as required of the subject matter of the claimed invention.

The applied art against the claims is directed to the claimed subject matter because it does teach licorice extract which is water-insoluble and free from glycyrrhizinic acid. Note page 268, "METHODS" and under "Materials" subsection, lines 1-7, licorice extract free of glycyrrhizinic acid and it is insoluble because it is obtained the same way Applicant obtains their alcoholic extract. Both Applicant and Fuhrman use ethanol to obtain the licorice extract. Further, it is water insoluble because at page 274, first column, "DISCUSSION" section, line 10, the licorice extract is disclosed to lack water-soluble constituents.

Hence, the article noted at page 9 of the instant response and cited above, is not representative of evidence that relates to the claimed subject matter. Further, Fuhrman et al clearly teach that to study the mechanism involved in the antioxidative activity of licorice, the LDL was subjected to several different modes of oxidation, the licorice extract showed, antioxidant activity against LDL oxidation in all of these systems and inhibits initiation of LDL lipid peroxidation in the free radical generating systems.

However, in other modes propagation and not initiation of the lipid peroxidation process is inhibited. Note page 274, second column, all lines. Therefore, the lowering of a patient's risk to disease such as total cholesterol and LDL levels, blood glucose, blood pressure, and resulting cardiovascular diseases is inherent to the teachings by Fuhrman et al.

With respect to the second noted article at page 10 of the instant response, "Can garlic reduce levels of serum lipids? A controlled clinical study", the article is directed to garlic, and not licorice extract. However, successful results were obtained for using the garlic as an antioxidant to lower total blood cholesterol and LDL levels. These are at least two risk factors. Fuhrman et al clearly teach that licorice extract resulted in reduction in LDL susceptiability, note abstract, last eight lines of the abstract. This lowering of susceptibility of LDL inherently includes LDL susceptibility to aggregation and retention which are at least two of the risk factors as well. Also the lowering of total blood cholesterol and LDL levels are also considered to be anticipated by the teachings of the cited reference, Fuhrman et al. The lowering of the risk factors as claimed would be the result of administering the licorice extract of Fuhrman et al to a patient. Also the patient of the claims is not even required to be suffering from a risk factor or be susceptible to a risk factor. Fuhrman et al is the documentary evidence along with Applicant's second noted document above which teaches that antioxidants lower risk factors. Therefore, the examiner submits that a valid prima facie case of anticipation has been set forth as discussed above and of record. Thus, the rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 6, 8, 12, 14, 18, and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhrman et al, cited of record and above as well, for those reasons of record.

Response to Arguments

Applicant's arguments filed November 24, 2004, have been fully considered but they are not persuasive. It is noted that Applicant asserts that Fuhrman et al teach away from the present claimed invention. However, the study referred to be Applicant was only carried out for two weeks, and although no significant change could be found in the LDL-cholesterol and in certain other characteristics such as blood count, coagulation tests, or renal or liver function tests, it should be noted that this study was conducted on young healthy humans so the rate of lipid peroxidation was most likely normal which may explain why no changes were observed. However, in the study on the atherosclerotic mouse successful results were observed because of increased lipid peroxidation.

Note page 273, first and columns, all lines. Note that the lesion is significantly smaller in B of Figure 7, this is the patient receiving the licorice extract. This extract also does not contain glycyrrhizinic acid, note at page 268, at "METHODS" section, subsection "Materials" at lines 6-7 the term "licorice" in Fuhrman et al is referring to a licorice extract free of glycyrrhinic acid. Therefore, once again the alleged teaching away of Fuhrman et al is not deemed persuasive. The cited reference clearly sets forth

a prima facie case of obviousness and is not at all directed to an "obvious to try" type of teaching. Thus, the rejection is maintained.

Claims 9, 15 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhrman et al in view of the admitted prior art (see specification at page 1, lines 10-12) for reasons set forth in the Office action of September 8, 2004 and of record as noted above and set forth below.

Response to Arguments

Applicant's arguments filed November 24, 2004 have been fully considered but they are not persuasive. The argument that hypertension is not disclosed and that Fuhrman et al even in view of admitted prior art does not suggest or disclose treating this condition is noted.

However, the cited Fuhrman et al reference clearly does teach the administering of an amount of licorice extract which is demonstrated to be effective by Fuhrman for reduction of susceptibility of LDL to oxidation of which has been implicated in cardiovascular disease.

Hypertension has also been implicated in cardiovascular disease. Also the prior art has recognized glycyrrhizinic acid to be causative of hypertension. Further, Fuhrman et al teach a glycyrrhizinic acid free licorice extract, therefore, to treat hypertension would have been prima facie obvious. Thus, the rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8200.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah K. Ware
February 18, 2005

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1205